PI Protocol Checklist: Return to Clinical Research at CHOP

V July 24, 2020

PROTOCOL CHECKLIST: Return to Clinical Research at CHOP

The COVID-19 pandemic has resulted in pausing and halting of clinical research studies at Children's Hospital of Philadelphia. This checklist provides guidance to PIs for a gradual, staged ramp-up of clinical research at CHOP. The checklist is designed to help consider which of the four basic categories/phases of clinical research their study represents, and to ensure that necessary staff and infrastructure are in place to successfully perform research activities.

CATEGORY I: Currently permitted • Essential clinical trials, SARS-CoV-2 clinical research, fully remote clinical studies		
Joint institutional review complete/modified research plan approved	**No**	**Yes**
CATEGORY II: Currently permitted • In-person research visit CONCURRENT with clinical visit • Research/biobank samples may be collected provided the in-person research visit is concurrent with clinical visit AND the laboratory/Core team can accept the research sample		
In-person research visit is CONCURRENT with clinical visit	**No**	**Yes**
If samples are to be collected, laboratory team or designated Core lab can accept the research sample	**No**	**Yes**
Category III: Currently permitted • Category IIIA: Previously scheduled in-person research visits canceled due to COVID-19 study restrictions • Category IIIB: New in-person research visits.		
CHOP Research Institute has issued guidance ramping up to Category III	**No**	**Yes**
Category IV: Permitted July 27, 2020		
Clinical research visits involving healthy volunteers as study subjects	**No**	**Yes**
Checklist for all categories		
Research is coordinated with and approved by Division/Department, Lab or Core Head/Designee*	**No**	**Yes**
Study team has confirmed availability of necessary clinical services for the protocol required observations/endpoints	**No**	**Yes**
Where necessary, the Division/Department/Laboratory is accepting research personnel accompanying research study subjects	**No**	**Yes**
Sufficient PPE is available for study staff and research subjects/caretakers	**No**	**Yes**
Training to study staff on PPE use has been completed	**No**	**Yes**

Study team confirms with research subjects/caretakers they are comfortable with resuming in-person research visits	**No**	**Yes**
The PI has confirmed that the research team can complete the required in-person visits while adhering to current Research Institute staffing limitations	**No**	**Yes**
Study team has developed processes for COVID-19 screening for research study subjects	**No**	**Yes**
If the clinical research will take place outside of CHOP Main/Roberts, the study team has confirmed with the outside study site that the research is allowed to proceed and that the outside study site can accommodate the research staff needed to perform the proposed research.	**No**	**Yes**

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*Potential resources to contact to determine readiness for commencing research: (some services require both a technical and professional component)

Division/Department/Lab	Availability Confirmed for Study
Anesthesia	
Apheresis	
Audiology	
Behavioral Health	
Biorepository Lab	
Cardiology (ECHO, EKG, Cardiac MRI)	
Cardiac Care Unit (CCU)	
Cardiac ICU	
Cardiac Prep & Recovery	
Cellular Therapy	
CHPS	
Day Medicine	
Dialysis	
EEG/Neurology	
Fetal Surgery	
Genetics	
GI Suite	
IDS/Pharmacy	
IV Team/Vascular Services	
Laboratory/Pathology	
Occupational Therapy	
Oncology Day Hospital	
Operating Room	
Ophthalmology	
Post Anesthesia Care Unit (PACU)	
Progressive Care Unit (PCU)	
Physical Therapy	
Pulmonary/PFT	
Radiology	
Respiratory	
Sedation	
Speech Pathology	